



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/038,894	03/11/1998	ROLAND STOUGHTON	24730-2202	8909

24961 7590 01/12/2004

HELLER EHRMAN WHITE & MCAULIFFE LLP
4350 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122-1246

EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
----------	--------------

1654

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/038,894	Applicant(s) STOUGHTON ET AL.	
	Examiner Michael V. Meller	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18,32-36,38,41 and 42 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-18,32-36,38,41 and 42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The election of species of record is maintained for the reasons of record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 32-36, 38, 41, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has argued that there is some confusion concerning prevention versus curing. The claims are drawn to prevention. Prevention of a disease or disorder is a very high standard of enablement for diseases such as cancer and AIDS. The claims read on such diseases. There is no known way to prevent or cure cancer. Can applicant truly demonstrate that cancer will not occur after such therapy is administered ? Applicant needs to show tests or other evidence which clearly demonstrate that the

Art Unit: 1654

disease/disorder is completely prevented. Without such evidence the claims are not enabled by the instant specification.

Claims 10-18, 32-36, 38, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are elevated using futhan, does not reasonably provide enablement for any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant argues that the specification provides numerous examples of different cell activation therapies and methods for identifying cell activation levels. As explained above there is a high standard of enablement for treating diseases such as cancer, AIDS, Alzheimer's, etc. For the above reasons the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-18, 32-36, 38, 41, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 32, it is not clear what "cell activation" is. Activation of what in the cell ? What activity is being activated, enzyme activity ? What kind of cell is activated ? Applicant still has not answered what is activated in the cell. What is so special about the cell being activated, for what ?

Further, it is not clear what the phrase, "if elevated" is relative to. How does one know if the elevation level has been met ? What level has to be reached to qualify as "elevated" ? What is a normal range ? What is this relative to ? Applicants comments are moot since they still have not defined this.

Also, it is not clear what is meant by "administering activation lowering therapy". Is this a method or a compound which is being administered ? Activation of what ? Applicant is still not clear what is being administered, a compound a method, what, What specifically is being administered to create such a desired effect.

Further, it is not clear what is meant by "preventing a disease or disorder" ? For the disease to be prevented the disease would have to be totally prevented, see above arguments. From reading the specification this is not what has happened. Thus, it is unclear how the claim is to be interpreted since prevention is not taught and one of ordinary skill in the art would assume that the disease is totally absent when it is prevented.

Claim Rejections - 35 USC § 103

Claims 10-18, 32-36, 38, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada 1 (of record), Okada 2 (of record), Yanamoto et al., or Yonekura et al. in view of Gibboni et al., Pick et al., Babcock et al., and Brunck et al.

Applicant has argued that the references do not teach assessing cell activation levels and then if elevated administering cell activation lowering therapy.

The references do teach that futhan is administered to a person having the claimed condition and the secondary reference show that such assessment is known in the art and that it would have been clearly within the purview of the skilled artisan to do such an assessment since doctors routinely do check ups like taking blood samples and check white blood cell count which would constitute assessment of the cell activation levels.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1654

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM